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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,794	04/13/2001	Lawrence D. Papsidero	3380/11127-US4	1046

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1642	9

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,794	PAPSIDERO ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *5-8,10-21 and 23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9,22 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-4, 9, 22 and 26 in Paper No. 8, filed Nov. 18, 2002, is acknowledged.

Claims 1-26 are pending.

Claims 5-8, 10-21, 23-25, drawn to non-elected inventions, are withdrawn from consideration.

Claim 9 was amended.

Claims 1-4, 9, 22 and 26 are examined on the merits.

Claim Objections

2. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 9 and 26 are objected to because they each depend from claims that have been withdrawn from consideration.

Claim Rejections - 35 USC § 112

3. Claims 1-4, 9, 22 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 9, 22 and 26 are indefinite because they are drawn to methods using compounds that are described as having "deduced" molecular weights and "deduced" isoionic points. The claims fail to recite what parameters are necessary for the deduction of the molecular weight or isoionic points.

4. Claims 1-4, 9, 22 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-4 are drawn to methods of treating breast diseases that are benign cystitis, benign hyperplasia, breast cancer and breast malignancies. The disease category of breast malignancy is interpreted to read on metastatic breast cancer. Claims 9 and 26 are drawn to methods of treating any breast disease. Claim 22 is drawn to methods of treating breast diseases that are inflammation, infection, and mastitis.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the

relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See Ex parte Forman, 230 USPQ 546, BPAI, 1986.

The guidance for the operation of the claimed methods is provided at page 5, lines 3-5. The specification contemplates general methods of treatment of breast disease, but fails to disclose any relationship between the expression of the chemokines comprising either of SEQ ID NO: 3, SEQ ID NO: 4 or SEQ ID NO: 5 and any breast disease state with the exception of breast cancer. Thus, there is no correlation between expression levels of breast diseases such as cystitis, hyperplasia, inflammation, infection or mastistis and expression levels of the proteins to be used in the claimed methods.

The specification also confines its contemplation of methods of treatment to the injection of patients with an antigenic portion of the disclosed chemokines. The assumption underlying this teaching is that an immunogenic reaction to the injected compound will then result in a treatment effect for cancer, cystitis, hyperplasia or malignancy. However, the specification fails to demonstrate data that an immunogenic reaction to the injected compounds would result in a treatment effect for any disease of the breast (even breast cancer). The specification fails to point to teachings in the prior art that would enable one of skill in the art to have a reasonable expectation of success in employing the claimed methods for the treatment of any breast disease, because it is not clear if the immunogenic response would result in destruction of diseased cells. There is no evidence that the disclosed chemokines are cellular markers for any disease of the breast, because the only data provided in the specification concerns measurement of chemokine levels in blood samples of breast cancer patients, indicating that the disclosed chemokines are secreted and do not remain with the breast cancer tissue. Furthermore, it is not clear that the

showing of the disclosed chemokines in blood samples of breast cancer patients is the result of the cancer itself, or the result of a treatment that the breast cancer patients received prior to the measurement of the disclosed chemokines. Thus, the specification appears to merely provide an invitation to experiment, and fails to enable one of skill in the art to practice the claimed inventions with a reasonable expectation of success.

5. Claims 1, 2, 4, 9, 22 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The basis for this rejection is that the breadth of the genus of compounds to be used in the claimed methods is not supported by an adequate written description, because the disclosure of SEQ ID NO: 1 is not representative of the genus of polypeptides comprising any of SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5.

The specification discloses SEQ ID NO: 1, which is a genus of 4 polypeptides, that are polypeptides that comprises any of SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5. The genus of polypeptides that comprises any of SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5 is far broader than the disclosure of SEQ ID NO: 1. This genus encompasses polypeptides such as splice variants of SEQ ID NO: 1 that are yet to be discovered, and have not been described in the specification. Furthermore, the specification appears to contemplate methods using polypeptides that consist of any of SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5 or that are those polypeptides that are fused to discrete polypeptides that have already been described in the art.

Because of the lack of written description for the broad genus of compounds, one of skill in the art would not understand that the inventor was in possession of the genus of polypeptides comprising any of SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5.

SEQUENCE LISTING

6. Applicant's attention is drawn to SEQ ID NO: 7. The STIC corrected to the response in the CRF for SEQ ID NO: 7, for field 212; the type was changed from NA to DNA. The CRF has been entered.

Conclusion

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
January 27, 2003

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